JC12 Rec'd PCT/PTC 2 1 OCT 2005

| "Express Mail" mailing label number EV 393132778 US | |
|--|--|
| Date of Deposit Dt. 21,205 | |
| I hereby certify that this paper or fee is being deposited with Addressee" service under 37 C.F.R. 1.10 on the date indic 1450, Alexandria, VA 22313-1450. | th the United States Postal Service "Express Mail Post Office to ated above and is addressed to the Commissioner for Patents, P.O. Box |
| Pringed Name | Signature Thomas |

PATENT APPLICATION IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Applicant:

Jeffry D. Watkins et al.

For:

CD20 Binding

Docket No.: X-16760A

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

As a means of complying with the duty of disclosure, Applicants submit an "Information Disclosure Citation In An Application" on a Form PTO-1449 (modified) and provide a copy of each of the listed documents for consideration by the Examiner.

Since this Statement is being filed in accordance with 37 C.F.R. 1.97(b), Applicants submit that no additional fee is required.

Applicants request consideration of this information.

Respectfully submitted,

Paula K. Davis
Attorney for Applicants
Registration No. 47,517

Phone: 317-433-3422

Eli Lilly and Company Patent Division, PKD P.O. Box 6288 Indianapolis, Indiana 46206-6288

October 19, 2005

10/553938 JC12 Rec'd PCT/PTC 21 OCT 2005

Sheet 1 of 4

| FORM PT | O 1449 | (modified) | Atty. Docket No. X-16760A | Serial No | , |
|-----------------------|---------------|--|--------------------------------------|--|--|
| INFORM. IN AN AF | | DISCLOSURE CITATION FION | First Applicant Jeffry D. Watkins | et al. | |
| | | | Filing Date | Group | |
| | | DOCUMENTS | | | |
| Examiner Initials* | Cite No. 1 | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines Where Relevant Pages or Relevant Figures Appear |
| | AA | US 2003/0003097 | 01-02-2003 | Reff et al. | |

09-24-2002

AB

US 6,455,043

| Examiner Initials* | Cite | Foreign Patent Document | | Name of Patentee or Applicant of Cited | Pages, Columns, Lines, Where | т6 . |
|-----------------------|------|---|------------|---|------------------------------|------|
| | No.1 | No. Country Code Number Hublication Date Kind Code5 (if known) No. Publication Date MM-DD-YYYY | Document | Relevant Passages or Relevant Figures Appear | | |
| | BA | WO 03/011878 | 02-13-2003 | Jean-Mairet et al. | | |
| | ВВ | WO 00/42072 | 07-20-2000 | Presta, L. | | |
| | BC | WO 99/54342 | 10-28-1999 | Jean-Mairet et al. | | |

Grillo-Lopez

| Examiner | /Ronald Schwadron/ | Date Considered | 09/12/2008 |
|-----------|--------------------|-----------------|------------|
| Signature | | | |

this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents ents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the

two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Skind of (see-little 000 (WPIO 2850000 5.3.). For Explanes prices accountment, but the propriet on the Compare must prope on the Compare must provide a set of the Compare must provide a

Sheet 2 of 4

| ORM PTO |) 1449 (n | nodified) | Atty. Docket No. X-16760A | Serjal N 7553 | 938 |
|-----------------------|---------------|--|--|--|-----|
| NFORMA' N AN APF | | SCLOSURE CITATION ON | First Applicant Jeffry D. Watkins et al. | , , , , | 8 |
| - And | | | Filing Date | Group | ** |
| | | | LITERATURE DOCU | | |
| Examiner Initials* | Cite No. I | Include name of the author (in CAI (book, magazine, journal, serial, sy | in CAPITAL LETTERS), title of the article (when appropriate), title of the item rial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published. | | |
| | CA | AME-133, "Superior Potency Compared to Rituxan® in Ex Vivo Model," Retrieved on June 14, 2004 from website http://www.amevolution.com/Development. | | | |
| | СВ | "AURISTATIN E ADCs, Seattle Genetics," retrieved on June 14, 2004 from website http://www.iddb.com. | | | |
| | СС | BLAKE, D. et al., "Metal Binding Properties of a Monoclonal Antibody Directed Toward Metal-Chelate Complexes." The Journal of Biological Chemistry, Vol. 271, No. 44, pp. 27677-27655, 1996. | | | |
| | CD | | et al., "The Human Immunogle ACs)." Gene, Vol. 191, pp. 17: | | |
| | CE | "(BW) (CA-GENENTECH) Humanized Anti-CD20 Ant 2004 from website http://ww | IDEC) (DNA) (IDPH) Genenti body Development Collaborat ww.businesswire.com. | ech and IDEC Announce ion," retrieved on June 14, | |
| | CF | | xa/GlaxoSmithKline." Curren | t Opinion in Investigational | |
| | CG | CHIU, YA-WEN et al., "Se a Monoclonal Antibody: An Anal. Chem, Vol. 73, pp. 54 | lective Binding of Polychlorina alysis by Kinetic Exclusion Flu 177-5484, 2001 | ited Biphenyl Congeners by iorescence Immunoassay." | |
| | СН | DALL' ACQUA et al., "Inc | reasing the Affinity of a Huma quences." The Journal of Imm | | |
| | CI | EDWARDS, J. and Cambrid Following a Protocol Design No. 2, pp. 205-211, 2001. | lge, G., "Sustained Improvement to Deplete B Lymphocytes | nt in Rheumatoid Arthritis " Rheumatology, Vol. 40, | |
| | CJ | "GENMAB Announces Hu- website http://www.genmab | max-CD20 Program," retrieved .com. | on June 14, 2004 from | 7 |
| | CK | "GENMAB: Selected Genm http://www.genmab.com. | ab Literature," retrieved on Ju- | ne 14, 2004 from website | |
| | CL | Collaboration," retrieved on | Announce Humanized Anti-CE June 23, 2003 from website h | tp://biz.yahoo.com. | |
| | СМ | | ing the Serum Persistence of ar echnology, Vol. 15, pp. 637-64 | | |

*EXAMINER: Install it reterence consistence. Whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patient Documents at www.nsgoo.gov or MPEP 901,04. Sector Office that issued the document, by the

Apparatus insuper custom designation in fauncier (optionals). Seek from to Code or to Ley 10 or term (account for Code or to Ley 10 or term (account for Code or to Ley 10 or term (account for Code or to Ley 10 or

10/553938 JC12 Rec'd FCT/FTC 21 OCT 2005

Sheet 3 of 4

| | CN | HONGO, J. et al., "Characterization of Novel Neutralizing Monoclonal Antibodies Specific to Human Neurturin." Hybridoma, Vol. 19, No. 4, pp. 303-315, 2000. | |
|-----|-----|--|---|
| i e | СО | "HUMAX-CD20," retrieved on June 14, 2004 from website http://www.iddb.com. | |
| | CP | KAWASAKI, K. et al., "Evolutionary Dynamics of the Human Immunoglobulin k Locus and the Germline Repertoire of the Vk Genes." Eur. J. Immunol., Vol. 31, pp. 1017-1028, 2001. | |
| | CQ | KAWASAKI, K. et al., "One-Megabase Sequence Analysis of the Human Immunoglobulin λ Gene Locus." Genome Research, Vol. 7, pp. 250-261, 1997. | - |
| | CR | KHOSRAVIANI, M. et al., "Binding Properties of a Monoclonal Antibody Directed Toward Lead-Chelate Complexes." Bioconjugate Chem. Vol. 11, pp. 267-277, 2000. | |
| * | CS | KIM, Jin-Kyoo et al., "Mapping the Site on Human IgG for Binding of the MHC Class 1-Related Receptor, FcRn." Eur. J. Immunol., Vol. 29, pp. 2819-2825, 1999. | |
| 7 | CT | "IBRITUMOMAB TIUXETAN," retrieved on June 14, 2004 from website http://www.iddb.com | |
| | CU | ILLIDGE, T. and BAYNE, M., "Antibody Therapy of Lymphoma." Expert Opin. Pharmacother., Vol. 2, No. 6, pp.953-961, 2001. | |
| | CV | MEDESAN, C. et al., "Comparative Studies of Rat IgG to Further Delineate the Fc: FcRn Interaction Site." Eur. J. Immunol., Vol. 28, pp. 2092-2100, 1998. | |
| - | CW | POWERS, D. et al., "Expression of Single-Chain Fv-Fc Fusions in <i>Pichia Pastoris.</i> " Journal of Immunological Methods, Vol. 251, pp. 123-135, 2001. | |
| | CX | "R-1594," retrieved on June 14, 2004 from website http://www.iddb.com. | |
| 7 | CY | "RITUXIMAB," retrieved on June 14, 2004 from website http://www.iddb.com. | |
| | CZ | SCHABLE and ZACHAU, "The Variable Genes of the Human Immunoglobulin χ Locus." Biol. Chem. Hoppe-Seyler, Vol. 374, pp. 1001-1022, 1993. | : |
| | CAA | SELDIN, D., "Techniques for Using Bexxar for the Treatment of Non-Hodgkin's Lymphoma." Journal of Nuclear Medicine Technology, Vol. 30, No. 3, pp. 109-114, 2002. | |
| | CAB | SHIELDS, R. et al., "High Resolution Mapping of the Binding Site on Human IgG1 for FcyRI, FcyRII, FcyRIII, and FcRn and Design of IgG1 Variants with Improved Binding to the FcyR." The Journal of Biological Chemistry, Vol. 276, No. 9, pp. 6591-6604, 2001. | |
| | CAC | STEIN, R. et al., "Characterization of a New Humanized Anti-CD20 Monoclonal Antibody, IMMU-106, and Its Use in Combination with the Humanized Anti-CD22 Antibody, Epratuzumah, for the Therapy of Non-Hodgkin's Lymphoma." Clinical Cancer Research, Vol. 10, pp. 2868-2878, 2004. | • |
| | CAD | "TOSITUMOMAB," retrieved on June 14, 2004 from website http://www.iddb.com. | |
| | | | |

| Examiner | | Date Considered | |
|-----------|--------------------|-----------------|------------|
| Signature | /Ronald Schwadron/ | | 09/12/2008 |
| | | | |

this form where communication opplicas.

Applicant's unique discovered and properties.

Applicant's unique discovered and properties.

Applicant's unique discovered and properties.

Applicant's unique discovered and properties of the properties o

occurrent by the appropriate synthesis is infected on the document undor VPD/C Standard ST in 61 possible. **Approximation updates a contract of the first possible of the standard sta

10/553938 JC12 Rec'd PCT/PTC 21 OCT 2005

Sheet 4 of 4

| | CAE | UMANA, P. et al., "Engineered Glycoforms of an Antineuro-blastoma IgG1 with Optimized Antibody-dependent Cellular Cytotoxic Activity." Nature Biotechnology, Vol. 17, pp. 176-180, 1999. | |
|---|-----|--|-----|
| 1 | CAF | VASSEROT, A. et al., "Optimization of Protein Therapeutics by Directed Evolution." Drug Discovery Today, Vol. 8, No. 3, pp. 118-126, 2003. | |
| | CAG | WU, H., "Humanization of a Murine Monoclonal Antibody by Simultaneous Optimization of Framework and CDR Residues." J. Mol. Biol., Vol. 294, pp. 151-162, 1999. | - 4 |

| Examiner | | Date Considered | 09/12/2008 |
|-----------|--------------------|-----------------|------------|
| Signature | /Ronald Schwadron/ | | 03/12/2000 |

I Applicant's unique clusion designation number (options). ² See Kinds Codes of USPTO Patent Documents at <u>saven unplo optr</u> or MPEP 901.00. ³ Ener Office that issued the document, by the two-less time of WPMO Standard ST.3. ⁵The Tapuaces patent electromate and excurses the patent p